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REMARKS

1. Status of the Application

Claims 1-5, 7-19, and 24-38 are pending in the present application.

Claims 1, 7-10, 12-15, 17-19, 26, 27, 31, and 35 have been added to more clearly define subject matter which was invented by Applicant. Unless otherwise noted, these claims have been amended without acquiescing to Examiner's arguments, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG)[1], and without waiving the right to prosecute the unamended (or similar) claims in another application. The amendments are not intended to narrow the scope of the Claim within the meaning of *Festo*[2].

Claims 1-5, 7-19, and 24-38 have been rejected on the following grounds:

1. Claims 1-5, 7-19, and 24-38 stand rejected under 35 U.S.C. §112, first paragraph as nonenabled;

2. Claims 35, 27, and 38 stand rejected under 35 U.S.C. §102(b) as anticipated by Lievense et al. (EP 0779033); and

3. Claims 1-5, 7-19, and 24-38 stand rejected under 35 U.S.C. 103(a), as obvious over Cook et al. (U.S. Pat. No. 5,760,082 and Lievense et al. (EP 0779033) in view of Cain et al. (WO 97/18320).

Applicant believes that the present amendments and the following remarks traverse the Examiner's rejection of the claims. These remarks are presented in the same order as they appear above.

1. The Claims are Enabled

Claims 1-5, 7-19, and 24-38 stand rejected under 35 U.S.C. §112, first paragraph as nonenabled. Applicant's contend that the Examiner has not established a *prima facie* case of nonenablement. In making a nonenablement rejection, the burden is on the Examiner to make a *prima facie* case of nonenablement that is well grounded in scientific reasoning or evidence.

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[1] 65 Fed. Reg. 54603 (September 8, 2000).

[2] *Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.2d 588 (Fed. Cir. 2000).

See In re Wright, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993); *See also* MPEP §706.03 and §2164.04. This is because without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling (*Id.* at 1513).

The Examiner has not made properly reasoned and supported statements explaining failure to comply with 35 U.S.C. §112, paragraph 1. The Examiner states at page two of the Office Action that the definition of volatile organic compounds encompasses "any non-polymeric organic compounds, including fatty acid and their esters, e.g., CLA or its esters." However, the definition goes on to state that the volatile organic compounds are produced from the oxidation of CLA. Examples of such organic compounds include pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan and octanol.[3] By not including this additional description, the Examiner has presented the language cited in the Office Action out of context. Nevertheless, without acquiescing to the Examiner's rejection and in order to advance the Applicant's business interests, and while reserving the right to prosecute the claims as drafted (or similar claims) in the future, Applicant's have amended the claims to specify that the volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof. Accordingly, Applicants believe the Claims are in condition for allowance.

2. The Claims are not Anticipated

Claims 35, 27, and 38 stand rejected under 35 U.S.C. §102(b) as anticipated by Lievense et al. (EP 0779033). Applicant's respectfully disagree. The Federal Circuit has stated the relevant analysis for anticipation as follows:

> A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference."[4]

At page three of the Office Action, the Examiner states that "Lievense teach a composition comprising CLA moiety which does not affect the smell or taste of the composition. The CLA moiety may be a mixture of free CLA and CLA triglyceride."

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[3] Specification, page 9, lines 10-15.

[4] *Verdegaal Bros. V. Union Oil Co. Of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants respectfully submit that distinct differences exist between the methods used to produce the CLA compositions of the present invention and those utilized by Lievense et al. As a result of these differences the compositions of Lievense et al. would have had a sufficient level of volatile organic compounds to affect the taste and smell of the composition. Lievense et al. describe at column 5, lines 38-58 of their specification that they obtained CLA from a commercially available mixture of free fatty acids using a prior art non-aqueous alkali isomerization method. However, as detailed in the specification at page 23, lines 6-15, CLA does not form peroxide breakdown products as do non-conjugated fatty acids. Instead, CLA is oxidized to form volatile organic compounds such as hexane. The problem of oxidation is most likely caused likely caused by metal ion contamination in the starting material. Applicants solved this problem by using a combination of methods, including, but not limited to addition of metal oxidant chelators and removal of pro-oxidants by methods including distillation and treatment with adsorbing agents (Specification, page 24, lines 20-25). As demonstrated in the Specification, these treatments are necessary to prevent the oxidation of CLA into compounds that affect the taste and smell of CLA compositions. Because Lievense et al. did not recognize this problem and did nothing to protect their CLA compositions from oxidative breakdown, their compositions cannot anticipate the compositions of the present invention. Accordingly, Applicants respectfully request that the Examiner remove this ground of rejection and pass the Claims to allowance.

3. The Claims are Not Obvious

Claims 1-5, 7-19, and 24-38 stand rejected under 35 U.S.C. 103(a), as obvious over Cook et al. (U.S. Pat. No. 5,760,082 and Lievense et al. (EP 0779033) in view of Cain et al. (WO 97/18320). Applicants respectfully submit that the Examiner has not made a prima facie case of obviousness. A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles

Applicants to allowance of the claims in issue.[5] In addressing this rejection, Applicants focus on the independent claims since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent therefrom.[6]

a. References do not Teach All of the Elements of the Claims

Applicants respectfully submit that the references cited by the Examiner do not teach each element of the claims. The Examiner admits at page 4 of the Office Action that "The primary references do not teach expressly the employment of ascorbic acid or particularly point out the amount of VOC." The Examiner then cites Cain as evidence that CLA is known is to be sensitive to oxygen and that addition of an antioxidant such as vitamin C to CLA is recommended. However, Applicants note that Cain is completely silent with respect to VOC content of their compositions. Thus none of the references teach this element.

Furthermore, Cain et al. groups CLA with other polyunsaturated fatty acids. As described above in Section 2, polyunsaturated fatty acids generally undergo peroxidation reactions. In contrast to normal polyunsaturated fatty acids, CLA undergoes oxidation form breakdown products. The cited references, including Cain, fail to appreciate this problem and thus offer no guidance for solving it. As taught in Applicants specification, the problem of oxidation is most likely caused likely caused by metal ion contamination in the starting material. Applicants solved this problem by using a combination of methods, including, but not limited to addition of metal oxidant chelators and removal of pro-oxidants by methods including distillation and treatment with adsorbing agents (Specification, page 24, lines 20-25). As demonstrated in the Specification, these treatments are necessary to prevent the oxidation of CLA into volatile organic compounds that affect the taste and smell of CLA compositions.

None of the cited references teach the removal of pro-oxidants by methods such as distillation and treatment with adsorbing agents. The Examiner mistakenly focuses on the use of antioxidants for preventing the oxidation of CLA, thereby ignoring the teachings in the specification that the antioxidants must be used in combination with other methods in order to

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[5] *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

[6] §MPEP 2143.03.

produce the claimed compositions. The Examiner apparently attempts to overcome this deficiency in the references by reasoning on pages 4-5 of the Office Action that "Regarding to the limitation about the amount of VOC, since the prior art teach that the food products containing CLA do not have any sensoric property caused by VOC, the amount of VOC is reasonably believed to be very low. The amount of VOC claimed herein is either within the scope of the prior art or an obvious variation of the prior art, lacking the criticality to the final products."

Applicants respectfully submit that this statement does not cure the deficiencies of the cited references. As a preliminary matter, under the law, an Examiner is **not** "one skilled in the art." (*See, Stratoflex, Inc., v. Aeroquip Corp.*, 218 USPQ 871, 879 [Fed. Cir. 1983]). Consequently, the Examiner's own views regarding the obviousness of the presently claimed cells cannot enter into the determination of obviousness. Therefore, the Examiner's "reasonable belief" that the amount of VOC is "very low" is not evidence upon which a prima facie case of obviousness can be based. The Examiner is urged to provide such evidence either by citation to a prior art reference or by submitting an affidavit substantiating his qualification to make such a conclusion. Likewise, the Examiner's statement that "The amount of VOC claimed herein is either within the scope of the prior art or an obvious variation of the prior art, lacking the criticality to the final products" also has no obvious basis in the cited prior art. Thus, the Examiner is impermissibly interjecting his own views on obviousness into the rejection. Again, the Examiner is urged to provide such evidence either by citation to a prior art reference or by submitting an affidavit substantiating his qualification to make such a conclusion. Otherwise, a prima facie case of obviousness is not established and the claims must be passed to allowance.

Next, Applicants again point out that the Examiner's statements on pages 4-5 of the Office Action do nothing to address the fact that the Applicants solved the problem of preventing the oxidation of CLA into volatile organic compounds. The Examiner has completely ignored the teachings in the Specification that metal ions must be removed from the compositions (e.g., by distillation or adsorption) in order to avoid the development of breakdown products. Since none of the cited references teach these processes, the compositions described in those references cannot anticipate or make obvious the compositions of the present invention. Finally, as to the Examiner's suggestion that the

claimed VOC levels are not critical to CLA compositions, Applicants respectfully submit that if the CLA is going to be administered orally or in a food product the level of VOCs is important as these compounds affect the palatability of the compositions.

Accordingly, Applicants respectfully submit that the references cited by the Examiner do not teach each element of the Claims and respectfully request that the claims be passed to allowance.

b. The Cited References do not Provide a Reasonable Expectation of Success

The cited references do not provide a reasonable expectation of success for obtaining the claimed compositions. The Federal Circuit has held that "obvious to experiment" is not the standard for obviousness. *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988). The Dow court made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art." *Id.* at 1531 (Emphasis added).

As described in detail above, the cited prior art references do not recognize the problem (i.e., metal ions causing the accumulation of volatile organic compounds) solved by the inventors of the present application. Thus, these references cannot provide a reasonable expectation of success in producing the claimed compositions. In particular, the cited references do not recognize or provide methods for removing metal ion contaminants from their compositions. The failure to do so results in the oxidation of CLA into volatile organic compounds such as those specified in the Claims. The Examiner's unsupported statements about the level of volatile organic compounds in the prior art compositions do not cure the deficiencies in the references. In conclusion, the Applicants submit that one skilled in the art would not believe that a reasonable expectation of success existed for arriving at the claimed invention. Therefore, a prima facie case of obviousness has not been established and the claims should be passed to allowance.

Conclusion

All grounds of rejection and objection of the Office Action of August 14, 2001 having been addressed, reconsideration of the application is respectfully requested. It is respectfully

submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: November 14, 2001

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APPENDIX I

MARKED-UP VERSION OF REWRITTEN, ADDED, AND/OR CANCELLED CLAIMS

The following is a version of the claims pursuant to 37 C.F.R. §1.121 (c)(1)(ii) with markings showing changes made herein to the previous version of record of the claims.

IN THE CLAIMS:

1. (Amended once) A composition comprising an isomerized conjugated linoleic acid moiety, said composition containing less than 100 parts per million total of volatile organic compounds, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

7. (Amended once) The composition of claim 1, wherein said composition contains less than 50 parts per million total of said volatile organic compounds.

8. (Amended once) The composition of claim 1, wherein said composition contains less than 10 parts per million total of said volatile organic compounds.

9. (Amended once) The composition of claim 1, wherein said composition contains less than 5 parts per million total of said volatile organic compounds.

10. (Amended once) A food product comprising an isomerized conjugated linoleic acid moiety and an metal oxidant chelator, wherein said isomerized conjugated linoleic acid moiety contains less than 100 parts per million total of volatile organic compounds, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

12. (Amended once) The food product of claim 10, wherein said isomerized conjugated linoleic acid moiety contains less than 50 parts per million total of said volatile organic compounds.

13. (Amended once) The food product of claim 10, wherein said isomerized conjugated linoleic acid moiety contains less than 10 parts per million total of said volatile organic compounds.

14. (Amended once) The food product of claim 10, wherein said isomerized conjugated linoleic acid moiety contains less than 5 parts per million total of said volatile organic compounds.

15. (Amended once) A food supplement comprising a isomerized conjugated linoleic acid moiety and an metal oxidant chelator, wherein said isomerized conjugated linoleic acid moiety contains less than 100 parts per million total of volatile organic compounds, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

17. (Amended once) The food supplement of claim 15, wherein said isomerized conjugated linoleic acid moiety contains less than 50 parts per million total of said volatile organic compounds.

18. (Amended once) The food supplement of claim 15, wherein said isomerized conjugated linoleic acid moiety contains less than 10 parts per million total of said volatile organic compounds.

19. (Amended once) The food supplement of claim 15, wherein said isomerized conjugated linoleic acid moiety contains less than 5 parts per million total of said volatile organic compounds.

26. (Amended once) The food product of Claim 24, wherein said conjugated linoleic acid moiety contains less than 100 ppm volatile organic compounds, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

27. (Amended once) The food product of Claim 24, wherein said conjugated linoleic acid moiety contains less than 5 ppm of said volatile organic compounds.

31. (Amended once) A food product comprising an isomerized conjugated linoleic acid moiety, said conjugated linoleic acid moiety having a sufficiently low volatile organic compound concentration so that the taste and smell of said food product is not affected, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

35. (Amended once) A composition comprising an isomerized conjugated linoleic acid moiety, said conjugated linoleic acid moiety having a sufficiently low volatile organic compound concentration so that the taste and smell of said composition is not affected, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

APPENDIX II

CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS AS AMENDED IN THIS COMMUNICATION

The following is a list of the claims as they would appear following entry of this amendment.

1. (Amended once) A composition comprising an isomerized conjugated linoleic acid moiety, said composition containing less than 100 parts per million total of volatile organic compounds, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

2. The composition of claim 1, wherein said isomerized conjugated linoleic acid moiety is a free fatty acid.

3. The composition of claim 1, wherein said isomerized conjugated linoleic acid moiety is an alkyl ester.

4. The composition of claim 1, wherein said isomerized conjugated linoleic acid moiety is a triacylglyceride.

5. The composition of claim 1, wherein said composition further comprises a metal oxidant chelator.

7. (Amended once) The composition of claim 1, wherein said composition contains less than 50 parts per million total of said volatile organic compounds.

8. (Amended once) The composition of claim 1, wherein said composition contains less than 10 parts per million total of said volatile organic compounds.

9. (Amended once) The composition of claim 1, wherein said composition contains less than 5 parts per million total of said volatile organic compounds.

10. (Amended once) A food product comprising an isomerized conjugated linoleic acid moiety and an metal oxidant chelator, wherein said isomerized conjugated linoleic acid moiety contains less than 100 parts per million total of volatile organic compounds, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

11. The food product of claim 10, wherein said moiety is selected from the group consisting of a triacylglyceride, a free fatty acid, and an alkyl ester.

12. (Amended once) The food product of claim 10, wherein said isomerized conjugated linoleic acid moiety contains less than 50 parts per million total of said volatile organic compounds.

13. (Amended once) The food product of claim 10, wherein said isomerized conjugated linoleic acid moiety contains less than 10 parts per million total of said volatile organic compounds.

14. (Amended once) The food product of claim 10, wherein said isomerized conjugated linoleic acid moiety contains less than 5 parts per million total of said volatile organic compounds.

15. (Amended once) A food supplement comprising a isomerized conjugated linoleic acid moiety and an metal oxidant chelator, wherein said isomerized conjugated linoleic acid moiety contains less than 100 parts per million total of volatile organic compounds, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

16. The food supplement of claim 15, wherein said moiety is selected from the group consisting of a triacylglyceride, a free fatty acid, and an alkyl ester.

17. (Amended once) The food supplement of claim 15, wherein said isomerized conjugated linoleic acid moiety contains less than 50 parts per million total of said volatile organic compounds.

18. (Amended once) The food supplement of claim 15, wherein said isomerized conjugated linoleic acid moiety contains less than 10 parts per million total of said volatile organic compounds.

19. (Amended once) The food supplement of claim 15, wherein said isomerized conjugated linoleic acid moiety contains less than 5 parts per million total of said volatile organic compounds.

24. A food product comprising a conjugated linoleic acid moiety and a metal oxidant chelator.

25. The food product of Claim 24, wherein said metal oxidant chelator is selected from lecithin and ascorbic acid.

26. (Amended once) The food product of Claim 24, wherein said conjugated linoleic acid moiety contains less than 100 ppm volatile organic compounds, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

27. (Amended once) The food product of Claim 24, wherein said conjugated linoleic acid moiety contains less than 5 ppm of said volatile organic compounds.

28. The food product of Claim 24, wherein said conjugated linoleic acid moiety is an ester of conjugated linoleic acid.

29. The food product of Claim 24, wherein said conjugated linoleic acid moiety is a triglyceride containing conjugated linoleic acid.

30. The food product of Claim 24, wherein said conjugated linoleic acid moiety is a free fatty acid.

31. (Amended once) A food product comprising an isomerized conjugated linoleic acid moiety, said conjugated linoleic acid moiety having a sufficiently low volatile organic compound concentration so that the taste and smell of said food product is not affected, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

32. The food product of Claim 31, wherein said conjugated linoleic acid moiety is an alkyl ester.

33. The food product of Claim 31, wherein said conjugated linoleic acid moiety is a free fatty acid.

34. The food product of Claim 31, wherein said conjugated linoleic acid moiety is a triglyceride.

35. (Amended once) A composition comprising an isomerized conjugated linoleic acid moiety, said conjugated linoleic acid moiety having a sufficiently low volatile organic compound concentration so that the taste and smell of said composition is not affected, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

36. The composition of Claim 35, wherein said conjugated linoleic acid moiety is an alkyl ester.

37. The composition of Claim 35, wherein said conjugated linoleic acid moiety is a free fatty acid.

38. The composition of Claim 35, wherein said conjugated linoleic acid moiety is a triglyceride.